

Applicants respectfully point out that the Specification was appropriately corrected in the amendment filed November 6, 2002. This amendment properly placed each sequence into the sequence listing and amended the Specification to recite SEQ ID Nos. Applicants have attached a copy of the amendment, the sequence listing and the stamped and dated postcard indicating that the Office of Initial Patent Examination received all appropriate materials on November 6, 2002. Thus, Applicants respectfully submit that they are in full compliance with the sequence rules.

Restriction Requirement

Claims 1-33 are pending in the present application.

The Examiner has issued a Restriction Requirement, contending that multiple inventions are present in the instant application that do not form a single general inventive concept under PCT Rule 13.1. The Examiner has grouped these inventions as follows:

Group I - claims 1-18, 24, 27-29, 31, drawn to an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg.

Group II - claims 19-23, 27-29, drawn to a polynucleotide encoding an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg.

Group III - claims 25-29, drawn to an antibody against an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg.

Group IV - claim 30, drawn to use of antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg for the preparation of a pharmaceutical composition.

Group V - claims 30, drawn to use of a polynucleotide encoding an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg for the preparation of a pharmaceutical composition.

Group VI - claims 30, drawn to use of an antibody against an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg for the preparation of a pharmaceutical composition.

Group VII - claim 32, drawn to the use of an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg for treating a disorder.

Group VIII - claim 32, drawn to use of a polynucleotide encoding an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg for treating a disorder.

Group IX - claim 32, drawn to use an antibody against an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg for treating a disorder.

Group X - claim 33, drawn to use of an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg for the investigation of CRFR functions.

Group XI, claim 33, drawn to use of a polynucleotide encoding an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg for the investigation of CRFR functions.

Group XII - claim 33, drawn to use of an antibody against an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg for the investigation of CRFR functions.

Applicants respectfully traverse.

Applicants first point out that the International Preliminary Examination Report indicates that unity of invention is present. According to 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims without regard to the practice in national applications (MPEP 1850). Applicants therefore request reconsideration and removal of the Restriction Requirement.

The Examiner contends that the inventions listed as Groups I-XII do not related to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: in order for the inventions to have unity of invention it is necessary that the inventive concept be a contribution over the prior art. The Examiner correctly states that the inventive concept of Groups I-XII is an antagonist of CRFR2 lacking the 8 to 10 N-terminal amino acids of Svg. The Examiner then contends that since the present Specification discloses that the antagonist astressin is known in the prior art and is an antagonist of CRFR2 and that since Figure 1 in the present Specification discloses astressin lacks the 8 to 10 N-terminal acids of Svg, a CRFR2

antagonist lacking the 8 to 10 N-terminal amino acids of Svg cannot be considered novel or to involve an inventive concept. Applicants respectfully submit that the Examiner is simply wrong.

First, astressin is a completely different antagonist. The fact that the alignment of astressin and Svg along with rUcn, oCRF and h/r CRF, as shown in Figure 1, begins at amino acid number 13 of the Svg amino acid sequence is of no import. Using this type of faulty logic, any protein would make the instant invention non-novel and obvious as long as it contained the sequence LLR that could be aligned with the LLR amino acids present at positions 13-15 of the Svg sequence. In addition, the Specification indicates that the astressin antagonist binds with similar affinity to rCRFR1 and mCRFR2 β , whereas the Svg-derived peptides of the instant invention show low-affinity binding to rCRFR1, but high binding affinity to mCRFR2 β . Again, significant differences exist between the instant invention and astressin. In view of this, Applicants respectfully request reconsideration and removal of the Restriction Requirement.

In order to be fully responsive, however, Applicants select Group I for examination.

Species Election

The Examiner contends that the application contains claims directed to more than one species of the generic invention and that these species lack unity of invention because they do not

form a single general inventive concept under PCT rule 13.1. The Examiner refers to the paragraph bridging pages 17-18 of the Specification, which discloses that the antagonist astressin is known in the prior art and is an antagonist of CRFR2. He also contends that Figure 1 shows that astressin lacks the 8 to 10 N-terminal amino acids of Svg, thus destroying novelty and inventive concept. Applicants respectfully traverse.

Again, Applicants refer to the International Preliminary Examination Report which indicates that there is no problem with unity of invention. In his discussion, the Examiner again refers to the antagonist astressin as pointed out above, the fact that astressin lacks some portion of Svg is of no consequence, astressin is a separate molecule that has properties that differs significantly from those of the instant invention. Applicants urge the Examiner to reconsider and remove the election requirement.

In order to be fully compliant, however, applicants elect compound 11, i.e. the compound wherein Xaa₁=D-Phe and Xaa₂=His.

Accordingly, Applicants respectfully request early allowance of the claims.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), the Applicant respectfully petitions for a two (2) month extension of time for filing a response in connection with the present application and the required fee of \$420.00 is attached hereto.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson (Reg. No. 30,330) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By 
Leonard R. Svensson, #30,330

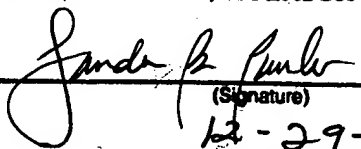
LRS/SWG/sbp
0147-0221P

P.O. Box 747
Falls Church, VA 22040-0747
(714) 708-8555

Attachments: Response filed November 6, 2002 - copy
Sequence Listing - Paper and CRF
Stamp Dated Postcard

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on: December 29, 2003
(Date of Deposit)

BIRCH, STEWART, KOLASCH & BIRCH, LLP


(Signature)
12-29-2003
(Date of Signature)

Papers Filed herewith on: Nov. 6, 2002
DOCKET NO.: 147-221P ATTY.: LRS
APPLICANT(S): SPLESS et al.
APPLN. NO: 09/244,441 FILED: May 11, 2001
PAT NO.:

- ☐ New Application with Transmittal Letter
☐ Utility ☐ Design ☐ CIP ☐ PCT ☐ Provisional
☐ Filing Under 37 CFR 1.53(b) ☐ CONT ☐ DIV
☐ Filing Under 37 CFR 1.53(d) (CPA)
☐ Filing Under 37 CFR 1.114(RCE)
☐ Specification Consisting of: _____ pages
☐ Combined Declaration & Power of Attorney
☐ Assignment / Cover Letter
☐ Letter to Official Draftsman
☐ Drawings _____ Sheets ☐ Formal ☐ Informal ☐ Red-Ink
☐ Completion of Filing Requirements, PCT/DO/EO/905
or Formalities Letter and Executed Declaration
☐ Priority Document(s) / Cover Letter, No. Doc. _____
☒ Amendment: for seq. Listing
☐ Transmtl Ltr ☒ Large Entity ☐ Small Entity
☐ Response
☐ Information Disc Stmnt. PTO-1449(s) _____
☐ Notice of Appeal ☐ Appeal Brief
☐ Issue Fee Transmittal
☐ FEES: _____
☐ Letter: _____
☒ Other: paper + disk copies
Listing. copy of Notice
with markings

Receipt is hereby acknowledged of the papers filed as
indicated in connection with the above identified case.
COMMISSIONER OF PATENTS AND TRADEMARKS
Due Date: 11-7-02
Handcarry: _____

DOCKET NO.

147-221P

